

Appl. No. 09/652,493
Amdt. Dated December 17, 2004
Reply to Office action of May 18, 2004

Amendments to the Claims:

What is claimed is:

Claim 1 (Currently amended): A method for ~~measuring potential tumorigenicity of~~
assaying mammalian cells to determine if tumor cells are present, comprising:

- a. providing a sample of medium surrounding said mammalian cells, and
- b. detecting the presence of a 120-130kD fragment of α -dystroglycan in the
medium, ~~said fragment having an Mr of 120-130kD~~, whereby the presence of the
fragment indicates that tumor cells are present ~~higher potential tumorigenicity~~.

Claim 2 (Currently amended): The method of claim 1, wherein said detecting comprises:

- a. adding to said sample a material selected from the group consisting of a
monoclonal antibody to α -dystroglycan ~~and laminin~~, and
- b. measuring that the size of the α -dystroglycan fragment is 120-130kD
~~detected~~.

Claim 3 (Currently amended): The method of claim 1, wherein said mammalian cells are
human mammary epithelial cells.

Claim 4 (Original): The method of claim 1, wherein said medium is blood serum.

Claim 5 (Currently amended): A method for measuring ~~potential~~ tumorigenicity of cells,
comprising:

- a. providing a sample of said cells, ~~and~~
- b. detecting the presence of α -dystroglycan on the surface of said cells,

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- c. providing a normal value for α -dystroglycan expression levels on cell surfaces; and
- d. comparing the detection levels of α -dystroglycan to said normal value,
whereby ~~the absence~~ a decrease in levels of α -dystroglycan on said cells of the
sample indicates a higher potential for tumorigenicity.

Claim 6 (Currently amended): The method of claim 5, wherein said detecting comprises:

- a. adding to said sample a monoclonal antibody specific for α -dystroglycan,
and
- b. measuring the amount of labeled α -dystroglycan detected.

Claim 7 (Original): The method of claim 5, wherein said cells are human mammary epithelial cells.

Claim 8 (Currently amended): The method of claim 5, wherein the step of providing a normal value comprises measuring said detecting comprises measurement of the amount of α -dystroglycan relative to the amount of β -dystroglycan on the surface of said cells,
wherein a relative decrease in the ratio of α -dystroglycan to β -dystroglycan indicates α -dystroglycan shedding and higher potential tumorigenicity.

Claims 9 – 21 (Canceled).

Claim 22 (Currently amended): A method of determining the likelihood that a patient has a tumor, by assaying proteolysed α -dystroglycan fragments shed from a cell into blood in patient serum, said method comprising the steps of:

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- a. contacting a serum sample to be assayed with a labeled antibody specific for ~~an~~ α -dystroglycan fragment, and
 - b. assaying the amount of bound label,
- whereby wherein said α -dystroglycan ~~fragments~~ bound to said labeled antibody ~~are~~ is positively correlated with existence of a tumor cell growth in the patient.

Claim 23 (Currently amended): The method of Claim 22, wherein the α -dystroglycan ~~fragment~~ is ~~an~~ a fragment of approximately 120 kD fragment.

Claim 24 (Currently amended): The method of Claim 22, wherein the α -dystroglycan ~~fragment~~ is ~~an~~ a fragment of approximately 60 kD fragment.

Claims 25 – 28 (Canceled).

Claim 29 (Currently amended): The method of claim 22, wherein said tumor cell is an epithelial cell tumor.

Claim 30 (Currently amended): The method of claim 29, wherein said epithelial cell tumor is a breast epithelial cell tumor.